CLAIMS

1.A composite material comprising :

(i) hyaluronic acid and/or hyaluronic acid derivatives,

(ii) a matrix of demineralised bone and/or biocompatible and biodegradable ceramics and/or bone of autologous or allogenic or animal origin.

2. The composite material according to claim 1 , wherein the hyaluronic acid in (i) is salified with organic or inorganic bases.

3. The composite material, according to anyone of claims 1 and 2, wherein said hyaluronic acid derivative in (i) is selected from the group consisting of:

A) esters of hyaluronic acid,

B) inner esters of hyaluronic acid with a percentage

C) amides of hyaluronic acid

D) O-sulphated derivatives of hyaluronic acid,

E) deacetylated derivatives of hyaluronic acid

F) percarboxylated derivatives of hyaluronic acid.

4. The composite material according to claim 3, wherein said hyaluronic acid ester is the benzyl ester.

5. The composite material according to claim 4 wherein the benzyl ester has a degree of esterification of from 50 to 100%.

6. The composite material according to claim 5, wherein the benzyl ester has a degree of esterification of from 75 to 100%.

7. The composite material as claimed in claim 3 wherein the hyaluronic acid inner esters have an esterification degree lower than 20%.

8. The composite material as claimed in claim 7, wherein the hyaluronic acid inner esters have an esterification degree comprised between 0.05 and 5%.

9. The composite material as claimed in claim 3 wherein the amidation degree of hyaluronic acid amides (C) is lower than or equal to 15%.

10. The composite material as claimed in claim 9, wherein the amidation degree is comprised between 0,1 and 15%.

11. The composite material as claimed in claim in claim 3 wherein the deacetylated hyaluronic acid has a percentage of deacetylation lower than or

equal to 30%.

12. The composite material as claimed in claim 3, wherein the percarboxylated hyaluronic acid (F) has a percarboxylation degree of between 0.1and 100%.

13. The composite material as claimed 12, wherein said percarboxylation degree is comprised between 25 and 75%.

14. The composite material according to anyone of claims 1-13, wherein the biocompatible and biodegradable ceramics is selected from the group consisting of hydroxyapatite and/or tribasic calcium phosphate and/or calcium sulphate.

15. The composite material according to anyone of claims 1-13, wherein the bone matrix is partially or completely demineralised.

16. The composite material according to anyone of claims 1-15 wherein the hyaluronic acid derivative has a molecular weight of between 200 and 750 kDs.

17. The composite material according to anyone 1-16 wherein the hyaluronic acid derivative is in a form selected from the group consisting of a non woven tissue, a sponge, a paste, granules, and powders.

18. A multilayer composite material comprising as the inner matrix the composite material according to anyone of claims 1-17 in association with at least one layer comprising a hyaluronic acid derivative.

19. The multilayer composite material according to claim 18 wherein the layers are 2.

20. The multilayer composite material according to claim 18 wherein the layers are 3.

21. The multilayer composite material, according to anyone of claims 18-20, wherein said hyaluronic acid derivative contained in the layer (s) is selected from the group consisting of:

A) esters of hyaluronic acid,

B) inner esters of hyaluronic acid with a percentage

C) amides of hyaluronic acid

D) O-sulphated derivatives of hyaluronic acid,

E) deacetylated derivatives of hyaluronic acid

F) percarboxylated derivatives of hyaluronic acid

22. The multilayer composite material according to anyone of claims 18 -20,

wherein said hyaluronic acid ester is the benzyl ester.

23. The multilayer composite material according to claim 20, wherein the benzyl ester has a degree of esterification of from 50 to 100%.

24. The multilayer composite material according to 23, wherein the benzyl ester has a degree of esterification of from 75 to 100%.

25. The multilayer composite material according to claim 21, wherein the hyaluronic acid inner esters have an esterification degree lower than 20%.

26. The multilayer composite material according to claim 25, the hyaluronic acid inner esters have an comprised between 0.05 and 5%.

27. The multilayer composite material according to claim 21, wherein the amidation degree of hyaluronic acid amides (C) is lower than or equal to 15%.

28. The multilayer composite material according to claim 27, wherein the amidation degree is comprised between 0,1 and 15%.

29. The multilayer composite material according to claim 21, wherein the deacetylated hyaluronic acid has a percentage of deacetylation lower than or equal to 30%.

30. The multilayer composite material according to claim 21, wherein the percarboxylated hyaluronic acid (F) has a percarboxylation degree of between 0.1 and 100%.

31. The multilayer composite material according to claims 30, wherein said percarboxylation is comprised between 25 and 75%.

32. The multilayer composite material according to anyone of claims 18-31, wherein the hyaluronic acid derivatives comprised in the layer(s) are in the form selected from the group consisting of: non woven material, woven material, and compact, perforated porous or microporous membranes and films.

33.The multilayer composite material according to anyone of claims 18-32, wherein the inner matrix is in the form of a sponge consisting of the benzyl ester of hyaluronic acid with a percentage of esterification ranging between 70 and 100%, containing inside said sponge:

- bone granules or powders that are autologous and/or allogenic and/or of animal origin, or

- granules or other two- or three-dimensional structures constituted by biodegradable ceramics or, lastly,
- partially or completely demineralised bone matrix.

34. The multilayer composite material according to claim 33, subsequently coated throughout with HA and/or the derivatives thereof in the form of a thin film and/or sponge, to favour the entry, distribution and adhesion of the cells that will migrate once they have been loaded therein.

35. The multilayer composite materials according to anyone of claims 18-34, wherein the inner matrix is in the form of sponges formed by the inner esters of HA containing inside them:

- bone granules and/or powders of autologous and/or allogenic type and/or of animal origin,
- biodegradable ceramics or
- partially or completely demineralised bone matrix.

36. The multilayer composite materials according to anyone of claims 18-34, wherein the inner matrix is in the form granules, spheres. powders and/or two- and three-dimensional structures of various shapes and sizes consisting of biodegradable ceramics that are coated/incorporated in a layer of HA subsequently cross-linked to form its inner ester (ACP) which thus covers all the ceramic structures.

37. The multilayer composite materials according to anyone of claims 18-34, wherein the inner matrix is in the form of pastes and/or gels consisting of HA derivatives enclosing bone powders and/or granules that are autologous and/or allogenic and/or of animal origin, or granules or other two- or three-dimensional structures constituted by biodegradable ceramics or, lastly, pastes and/or gels containing demineralised bone matrix.

38. The multilayer composite materials according to anyone of claims 18-34, wherein the inner matrix is in the form of fibres comprising the benzyl ester of HA with a percentage of esterification ranging between 50 and 100%, possibly associated with other natural polymers selected from collagen and cellulose and the derivatives thereof, or synthetic polymers selected from poly-lactic,

polyglycolic and poly-caprolactone acid, in association with demineralized bone matrix and hyaluronic acid.

39. The multilayer composite materials according to claim 38, wherein the matrix can be wetted with a solution of Hyaluronic acid ester , to render it more compact with the layers between which it is sandwiched.

40. The multilayer composite materials according to anyone of claims 38 and 39, wherein said matrix consists of fibres of hyaluronic acid benzylester having an esterification degree of 75% in amounts ranging from 10 to 50% and demineralised bone matrix in amounts ranging from 50 to 90% and htyaluronic acid having an average molecular weight ranging from 200 to 750 KDs in amounts ranging from 0.1 and 40%.

41. The multilayer composite material according to claim 40, wherein said matrix consist of fibres of hyaluronic acid benzylester having an esterification degree of 75% in amounts ranging from 14 to 24%, demineralised bone matrix in amounts varying between 60 and 80%, hyaluronic acid having an average molecular weight ranging from 500 to 700 KDs in amounts comprised between between 5 and 10%.

42. The multilatyer composite material according to anyone of claims 18-41, wherein said inner matrix is immersed to make the final matrix more compact and to fixable to the layer/s.

43. The multilayer composite according to claim 42 wherein said polymer is selected from:

- hyaluronic acid benzyl ester with a percentage of esterification of between 55 and 100%;
- fibrin glue,
- photocross-linkable polymers
- collagen and derivatives thereof.

44. The multilayer composite material according to anyone of claims 18-43. wherein the layer(s) comprise a hyaluronic acid ester.

45. The multilayer composite materials according to claim 44, wherein said hyaluronic acid is the benzylester with a percentage of esterification ranging between 50 and 100%.

46. The multilayer composite material according to claim 45, wherein said percentage degree is comprised between 75 and 100%.

47. The multilayer composite material according to anyone of claims 44-46, wherein the layers are in the form of: a non-woven material, containing fibres of the hyaluronic acid ester possibly associated with natural polymers selected from collagene and cellulose and the derivatives thereof, or synthetic polymers selected from poly-lactic acid, poly-glycolic acid and poly-caprolactone acid.

48. The multilayer composite material according to anyone of claims 44-46 wherein the layers are in the form of a woven material containing fibres of the hyaluronic acid ester, possibly subsequently immersed in a solution of hyaluronic acid.

49. The multilayer composite material according to anyone of claims 44-46, wherein the layers are in the form of compact perforated porous or microporous membranes and films.

50. The multilayer composite materials according to anyone of claims 18-49 further containing pharmacologically and/or biologically active ingredients.

51. The multilayer composite materials according to claim 50, wherein the pharmacologically active ingredients are selected from the group consisting of antibiotics, antineoplastics, anti-inflammatories, cytokines, vitamins and cytotoxic, cytostatic and antiviral agents.

52. The multilayer composite materials according to claim 50, wherein biologically active ingredients contain trophic, osteoinductive, angiogenetic factors.

53. The multilayer composite material according to claim 50, wherein the trophic, osteoinductive and angiogenetic factors contain BMP, TGF, PDGF, FGF, EGF, IGF and VEGF.

54. The multilayer composite material according to anyone of claims 18-53 loaded with bone marrow cells.

55. The multilayer, composite material according to anyone of claims 18-53, loaded with autologous and/or allogenic mesenchymal cells either undifferentiated or partially differentiated into osteoblasts.

56. The multilayer composite materials according to anyone of claims 18-53, loaded with autologous and/or allogenic mesenchymal cells that are completely differentiated into osteoblasts.

57. A process for preparing the multilayer composite material according to anyone of claims 18-54 comprising the following steps:

a) forming the inner matrix by associating hyaluronic acid and/or a hylauronic acid ester and demineralised bone matrix, and/or a biocompatible biodegradable ceramics and/or bone of autologous or allogenic type or of animal origin,

b) coupling the matrix with the layer(s),

c) fixing the matrix to the layer(s), in toto or by means of the outer edge.

58. The process according to claim 54, wherein step (c) is carried out by heat treatment .

59. The process according to claim 57 wherein step (c) is carried out by exposing the material coming step (b) to a needle-punching process.

60. The process according to claim 58 wherein step (c) is carried out by sewing the material coming from step (b) with thread made of hyaluronic acid and/or the derivatives thereof or another biocompatible and bioresorbable polymer.

61.A bone substitute or graft consisting of the composite material according to anyone of claims 1-17.

62. A bone substitute or graft consisting of the multilayer composite material according to anyone of claims 18-56.

63. The bone substitute or graft according to claim 62 in the form of a sandwich or bag.

64. The bone substitute or graft according to anyone of claims 61-63 for use in the regeneration or formation of bone tissue.

65. The bone substitute or graft according to anyone of claims 61-63 for use in surgery.

66. The bone substitute or graft according to anyone of claims 61-65 for use in spinal surgery.

67. The bone substitute or graft according to anyone of claims 61-65 for use in spinal surgery.

68. The bone substitute or graft according to anyone of claims 61-65 for use in maxillofacial surgery.

69. The bone substitute or graft according to anyone of claims 61-65 for use in surgery to the shoulder, hand and foot.

70. The bone substitute or graft according to anyone of claims 61-65 for use in dental surgery.

71.The bone substitute or graft according to anyone of claims 61-65 for use in oncological surgery.

72. The bone substitute or graft according to anyone of claims 61-65 for use in all types of orthopaedic surgery requiring the fusion of adjacent bones and then the formation of new bone tissue.

73. The bone substitute or graft according to claim 67 for use in fusing to two adjacent vertebral bodies.

74. The bone substitute or graft according to claim 67 for use in filling one or more vertebral bodies previously hollowed out.